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May 28, 1997

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RECEIVED
SEP 19 1997
P1:47

Elizabeth A. Yetley, Ph.D., R.D., Director
Office of Special Nutritionals
Center for Food Safety and Applied
Nutrition
Food and Drug Administration
200 C Street, SW, HFS-450
Washington, DC. 20204

Dear Dr. Yetley:

Rexall Sundown, Inc. ("Sundown") wishes to notify the Food and Drug Administration that it has marketed or will within the near future commence marketing dietary supplements which bear statements of nutritional support, pursuant to Section 6 of the Dietary Supplement Health and Education Act ("DSHEA"), Section 403(r) of the Federal Food and Drug Cosmetic Act ("the Act"). Please see the attachment for a listing of the dietary supplements and corresponding statements of nutritional support.

These statements are being accompanied by the required disclaimer pursuant to Section 403(r)(6)(C) of the Act. Two copies of this cover letter and its attachment are enclosed.

Very truly yours,

Deborah Shur Trinker

Deborah Shur Trinker
Director of Regulatory Affairs
and Corporate Counsel

DST/mw

Attachment

975-0162

LET678

DIETARY SUPPLEMENT	BRAND NAME	STATEMENT OF NUTRITIONAL SUPPORT
Chromium K6		For effective weight management along with proper diet and exercise. Chromium picolinate is a trace mineral that is essential for protein, carbohydrate and fat metabolism, as well as insulin function; chromium picolinate supplementation helps reduce body fat and increases body mass in moderately obese people.
Combination Product (Claims for Vitamin E, Niacin, Folate, Vitamin B-12, Zinc, Ginkgo Biloba, Gotu Kola, L-Glutamine, L-Tyrosine, Choline, Phosphatidyl Serine, Damiana)	Clear Thoughts™	A Dietary Supplement for enhanced memory and thinking power; part of a nutritional program to meet the mental alertness needs of adult men and women. Healthy individuals rely on their capacity to perform everyday tasks related to memory and cognition. The ability to remember what you did a few minutes ago or what you said an hour ago is called short-term memory. Short-term memory includes the ability to recall names, numbers and important words or phrases, and to concentrate on the task at hand. The key to optimal mental functioning is to stimulate the activity of neurotransmitting chemicals in the brain. Neuroscience research indicates that supplementation with specialized dietary supplements plays an important role in the activity and production of such chemicals and provides your body with the nutritional support it needs.
Ginseng Complex - (Claims for Siberian Ginseng, Panax Ginseng and Vitamin B-12)		Promotes energy and endurance.
Combination Product - (Claims for Chromium Picolinate; Lecithin; Choline; Inositol; Grapefruit Extract)	Weight Management Formula	For general well-being; healthy living; and active lifestyles. Lecithin acts as an emulsifying agent in the body, enabling fats to be dispersed in water and removed from the body.
CoQ-10 - (Claims for Coenzyme Q-10)	Cardiovascular Formula	For the heart and circulatory system; powerful antioxidant protection; and cellular energy. CoQ-10 works as a powerful antioxidant that protects cellular membranes from free radical damage that can lead to premature aging.
Combination Herbal Product - (Claims for Ginseng, Gotu Kola and Guarana)	Energy Formula	Helps promote healthy energy levels, optimum performance and active lifestyles.
Combination Multivitamin, Mineral & Herbal Product - (Claims for Saw Palmetto, Pygeum, Nettle, Zinc, Selenium, Vitamin E, Folic Acid, Vitamin B-12, Siberian Ginseng and Korean Ginseng)	Comprehensive Men's Formula	Saw Palmetto, Pygeum, Nettle, Zinc and Selenium for healthy prostate function; Vitamin E and Folic Acid for healthy heart function; and Siberian Ginseng, Korean Ginseng and Vitamin B-12 for energy and endurance.

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Combination Multivitamin, Mineral & Herbal Product - (Claims for Vitamin C, Vitamin E, Folic Acid, Ginkgo Biloba, Siberian Ginseng, Bilberry, Selenium and Zinc)	Comprehensive Women's Formula	Vitamin C, Vitamin E, Zinc and Selenium for immune protection; Vitamin E and Folic Acid for healthy heart function; and Ginkgo Biloba and Siberian Ginseng for mental alertness and concentration. Bilberry helps promote circulation and healthy eye function.
Multinutrient and Vitamin C	Cellular Essentials™	Cardiobasics is a multi-nutrient formula designed in accordance with recognized principles about the importance of cellular nutrition for good cardiovascular health. Bio-C Vitamin C is vital to production of collagen molecules that provide the stability necessary for proper cardiovascular function. Cellular Essentials provides essential nutrients to promote and maintain maximum stability and function of the blood vessel walls. The body's ability to maintain cellular function and cardiovascular health is dependent on many factors such as adequate nutrition and age. Cellular Essentials help promote important cell repair function of the cardiovascular system.
Saw Palmetto Complex - (Claims for Saw Palmetto, African Pygeum, Zinc and Nettles)		Promotes prostate and urinary well-being.
Shark Cartilage	Advanced Shark Cartilage 790	Both bovine cartilage and glucosamine help maintain healthy, mobile joints; promotes joint and connective tissue health.
Valerian Complex - (Claims for Valerian Root, Kava Kava and Passion Flower)		Promotes restful well-being.
Combination Vitamin and Herbal Product - (Claims for Vitamin C, Echinacea and Goldenseal)	Immune Function Formula	For healthy immune function, respiratory function and general well being. Echinacea, Goldenseal and Vitamin C help promote healthy immune and respiratory function. Echinacea provides superior herbal support for healthy immune function and promotes general well-being, especially during the cold and flu season. From the root of a small perennial plant native to eastern North America, Goldenseal contains a number of important alkaloids, including hydrastine, berberine and tetrahydroberberine. Goldenseal is reported to help maintain healthy respiratory function. This powerful antioxidant prevents free radical damage and provides protection for healthy cells and body systems.
Combination Product of Vitamin, Mineral, Herbal and Other Dietary Ingredients - (Claims for Glucosamine HCl, Alfalfa, Vitamin C, Zinc, Manganese and Copper)	Mobility Formula	For cartilage repair, healthy joint function and mobility and connective tissue health. The combination of glucosamine hydrochloride, vitamin C, zinc, manganese, copper and alfalfa helps maintain healthy, mobile joint function and connective tissue health. Glucosamine, a natural aminosugar found in the body, plays an important role in the repair and maintenance of cartilage. It is used in the formation of structural components,

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		such as tissues and fluids necessary in cartilage function, and is an essential component of many tissue molecules. Glucosamine also stimulate the production of a chondroitin sulfate, an important salt which provides lubrication to the joint. This fluid helps attract nutrients into the cartilage and acts as a shock absorber. Vitamin C is essential for the production and maintenance of collagen, the component of cartilage and a key to healthy bone and cartilage formation. Essential trace minerals, such as zinc, manganese and copper, are also required for maintaining bone metabolism and bone density. They also work to promote strong, healthy bone joints.
2916 / Combination of Enzymes - (Claims for Lipase, Cellulase, Amylase, Lactase, and Protease)	Enzygen®	Enzygen is a natural adjunct to digestion and proper nutrition. It helps release nutritional value from the good foods you already eat, and helps promote healthy digestive function.
St. John's Wort - (0.3% Hypericin)		St. John's Wort helps assist in mood enhancement. The leaves and flowers contain a variety of active compounds such as hypericin, flavonoids and tannins. Hypericin helps enhance mood by promoting a calming and soothing sense of well-being.
2297 Green Tea Extract - (50% Polyphenols)		Green Tea Extract provides superior antioxidant protection. It contains high amounts of polyphenols called catechins, which are potent antioxidant compounds. Catechins work to neutralize unstable substances called free radicals which can cause oxidative stress and damage to cells; supports healthy immune function.